(510(k) Summary) MAR 1 9 2014

Product: Speed XL™

Submitter Information

BioMedical Enterprises, Inc.
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Contact: Joe W. Soward

Date Prepared: December 3, 2013

Classification name: Single/multiple component metallic bone fixation appliances and accessories (21 CFR 888.3030)

Classification:	Class II
Product Code:	JDR
Common/Usual Name:	Bone Staple
Proprietary Name:	Speed XL™

Intended Use:

The Speed XL™ is indicated for:
Fracture and osteotomy fixation and joint arthrodesis of the hand and foot.

Substantial Equivalence:

The Speed XL™ is substantially equivalent to the predicate Speed Shift™ cleared in K124022.

Device Description

The Speed XL™ is for use in fracture and osteotomy fixation and joint arthrodesis of the hand and foot. The implant is designed so that it is delivered to the operating room in an "open" martensitic state. The implant is then transformed by room temperature after insertion, and contracts to a "closed" austenitic state. The implant does not require any external heating; it is completely transformed by room temperature.

This configuration change for the Speed XL™ consists of a change in device shape, including flattened bridge with wider dimension to be used in hand and foot procedures.

Technological Characteristics Comparison to the Predicates

Product Name:	New Device Speed XL™	Predicate Speed Shift™ (K124022)
Raw Material:	Nitinol, per ASTM F2063-12	Nitinol, per ASTM F2063-12
Bridge Lengths (mm):	20 and 25	15 and 20
Leg Lengths (mm):	20	20
Cross-section Dimensions (mm):	Leg: 1.80 x 2.06 Bridge: 1.85 x 3.52	1.80 x 2.00
Barbs:	Barbs on the legs	Barbs on the legs
Pilot Drill Hole Sizes (mm):	2.65	2.65
Heat Source:	Fully transformed at room temperature	Fully transformed at room temperature
Surface Finish:	Mechanical tumbling, acid cleaning, and chemical passivation.	Mechanical tumbling, acid cleaning, and chemical passivation.
Storage:	Sterile packaged and can be stored at room temp until used.	Sterile packaged and can be stored at room temp until used.

Performance Bench Testing:

Standard ASTM F564-10 (2010) was used to compare the pull-out strength of the new Speed XL™ to the predicate Shift™. Two lots with three samples each (n=3) were compared to similarly sized Speed Shift™ predicates. The results for the Speed XL™ yielded substantially equivalent pull-out resistance than the comparable predicate Speed Shift™ for similar sizes. (TR-02-129-1316)

Standard ASTM F564-10 (2010) was used to compare the mechanical strength of the Speed XL™ to the Speed Shift™. The largest and smallest Speed XL™ sizes were tested and compared to similar Speed Shift™ predicates. The Speed XL™ devices yielded substantially equivalent bending stiffness when compared to the Speed Shift™ predicates. (TR-01-129-1315)

Standard ASTM F2129-08 was used to compare the corrosion resistance of representative samples of the new Speed XL™ to the predicate Speed Shift™. Test results demonstrate the corrosion resistance is equivalent to the predicate Speed Shift™. (FWM # 13-08-30946, FWM # 13-08-31279, & FWM # 13-10-31866)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 19, 2014

BioMedical Enterprises, Incorporated
Mr. Joe W. Soward
Director, Quality, Compliance and Regulatory Affairs
14785 Omicron Drive, Suite 205
San Antonio, Texas 78245

Re: K133780
Trade/Device Name: Speed XL™
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: JDR
Dated: January 22, 2014
Received: January 23, 2014

Dear Mr. Soward:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Device Name: Speed XL™

Indications for Use

The Speed XL™ is indicated for:

Fracture and osteotomy fixation and joint arthrodesis of the hand and foot.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Casey L. Hanley, Ph.D.
Division of Orthopedic Devices